Overview Information	
Funding Opportunity Title	**Precision Medicine Initiative® Cohort Program Regional Medical Center Healthcare Provider Organizations (OT2)** https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/20160728-hpo.pdf
Funding Opportunity Number	OT-PM-16-003
Participating Organization	National Institutes of Health (NIH)
Components of Participating Organizations	This funding opportunity is part of the NIH Precision Medicine Initiative®. The funding opportunity will be administered by the National Center for Advancing Translational Sciences (NCATS) on behalf of the NIH.
Announcement Type	New
Related Notices	NOT-OD-15-159 Precision Medicine Initiative Cohort Program Recommendations Issued and Accepted OT-PM-16-001 Precision Medicine Initiative® Cohort Program Direct Volunteers Pilot Studies OT-PM-16-002 Communication Support for the Precision Medicine Initiative® Research Programs at NIH RFA-PM-16-001 Precision Medicine Initiative® Cohort Program Coordinating Center (U2C) RFA-PM-16-002 Precision Medicine Initiative® Cohort Program Healthcare Provider Organization Enrollment Centers (UG3/UH3) RFA-PM-16-003 Precision Medicine Initiative® Cohort Program Participant Technologies Center (U24) RFA-PM-16-004 Precision Medicine Initiative® Cohort Program Biobank (U24)
Funding Opportunity Purpose	The purpose of this funding opportunity is to invite applications from regional medical center healthcare provider organizations (RMC HPOs) to become partners with the Precision Medicine Initiative Cohort Program. The goal of the PMI Cohort Program is to build a research cohort of one million or more U.S. volunteers who are engaged as partners in a longitudinal, long-term effort to transform the understanding of factors contributing to individual health and disease. Applicants awarded under this opportunity will be responsible for managing engagement, enrollment and retention of their patients into the Cohort, performing physical evaluations and collecting biospecimens, and providing electronic health record data. HPOs will also be responsible for actively collaborating in the governance and

	scientific oversight of the PMI Cohort Program, through participation in working groups and other consortium activities. Awards made through this funding opportunity will support a 12-month, milestone-driven feasibility phase. Applicants successful under this mechanism may have the possibility of competing for a 4-year full implementation phase through a subsequent funding opportunity announcement (FOA) that will be issued in FY2017.
Funding Instrument	The funding instrument is the Other Transaction (OT) award mechanism: An OT award is not a grant, cooperative agreement or contract, and uses Other Transaction Authorities.
Funds Available	Actual amounts will depend on funds available, but should not exceed $4M in total costs for each OT2 award application.
Anticipated Number of Awards	NIH intends to fund three (3) awards in FY2016.

Key Dates

Award Project Period	The total project period will be one (1) year.
Post Date	July 29, 2016
Application Due Date	August 29, 2016 (5:00 pm local time)
Scientific/Technical Review Date	Review will be conducted immediately upon receipt of applications.
Award Timeline	Award will be made upon selection and award negotiation.

Application Instructions

Required Application Content	Applications must include sufficient detail to allow the NIH to assess the applicant's capabilities to provide the requested services. All applicants must address and integrate all task areas. Although not recommended, eligible organizations may submit multiple applications. Each application submitted must be distinct and address all task areas. Applications must include the following with the total application package not exceeding 25 pages: • Technical Approach: Not to exceed 15 pages. The technical approach should be based on the overall plans and activities identified in this funding opportunity. • Past Performance (Corporate/Organizational experience related to the funding opportunity): Not to exceed 3 pages. Applicants should describe the track record of performing the specialized work required in this project, including appropriate expertise and experience in meeting milestones and contributing to a large-scale consortium and past participation in collaborative research projects. • Key Personnel (Applicants should provide brief bios of key personnel): Not to exceed 4 pages. Each application must

	identify the Program Director/Principal Investigator (PD/PI) or multiple PDs/PIs, an IT/EHR Lead, and a Participant Engagement Lead. The level of effort these individuals anticipate committing to this project, if awarded, must be identified. Other key personnel should be included as well. An overall leadership structure and management plan must be included in this section. If there are multiple PDs/PIs, a leadership plan must be included. • PD/PI Experience: Not to exceed 1 page. Each PD/PI must describe previous experience in leading large projects. The applicant should include a description of each PD/PI's proven track record in leading large projects and in effective collaborations among the proposed participating sites. • Cost Proposal: Not to exceed 2 pages. Applicants must provide a milestone driven, cost allocated plan. Cost models can be cost-sharing, fixed price, adjustable (cost reimbursable) or a hybrid approach. A one page cover letter is not included in the 25 page limit, and is allowed. Appendices are not allowed.
Instructions for Application Submission	Applications must be submitted in a single email attachment in PDF (Adobe) format to Ms. Irene Haas, PMI Cohort Program Agreements Officer, at PMICPFOAInquiries@mail.nih.gov. Applications must be submitted by an authorized representative from your organization. Paper applications will not be accepted.
Eligibility Information	
Eligible Applicants	Organizations, including subaward partners, currently receiving funding support through the PMI Cohort Program as an HPO are NOT eligible to apply. The following entities are eligible to apply as an applicant organization: Higher Education Institutions • Public/State Controlled Institutions of Higher Education • Private Institutions of Higher Education The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education: o Hispanic-serving Institutions o Historically Black Colleges and Universities (HBCUs) o Tribally Controlled Colleges and Universities (TCCUs) o Alaska Native and Native Hawaiian Serving Institutions o Asian American Native American Pacific Islander Serving Institutions (AANAPISIs) Nonprofits Other Than Institutions of Higher Education • Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)

	• Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education) For-Profit Organizations • Small Businesses • For-Profit Organizations (Other than Small Businesses) Applicant organizations are encouraged to seek partnerships with all types of domestic organizations. Applicant organizations are required to use the PMI Cohort Program central Institutional Review Board (IRB). An IRB reliance agreement will be required for applicants being considered for funding.
Foreign Institutions	Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply. Foreign components are **not** allowed. Foreign components are defined as performance of any significant element or segment of the project outside of the United States either by the award recipient or by an individual employed by a foreign organization whether or not OT2 award funds are expended.
Application Review	
Objective Review Process	Applications will be evaluated for scientific and technical merit by an appropriate review group convened by the NIH, and will include expert non-federal and federal reviewers. Reviewers will evaluate applications based on the following: • Technical Approach • Past Performance • Key Personnel • PD/PI Key Personnel Experience • Cost Proposal Applicants will receive a brief written summary of the review 2-4 weeks after the review date.
Evaluation Process	In addition to technical and scientific merit, applications will be evaluated for programmatic priority. Programmatic priority will be given to applicants: • Representing geographic regions or populations that are currently not well-represented in the PMI Cohort Program • Reflecting the diversity of the American population within the proposed catchment area • Maintaining highly integrated and networked electronic health record systems with the ability to efficiently and effectively provide structured EHR data • Documenting proven leadership and strong collaborative

	teams • Indicating ready technical, clinical, and administrative capabilities to engage, enroll, examine, and retain the participants in the PMI Cohort Program. • Identifying a clear path to scale to 35,000 participants and all activities required therein by the end of the award period. After the review, applicants under consideration for award will be invited for an in-person "reverse site visit" at the NIH in Bethesda, Maryland, with NIH PMI Cohort Program key staff. Applicants should hold the dates of September 12th and 13th, 2016, for this activity.
Questions Regarding this Funding opportunity	Questions may be submitted via email to Irene Haas, PMI Cohort Program Agreements Officer (NCATS) at PMICPFOAInquiries@mail.nih.gov.
PMI Cohort Program Agreements Officer Contact	Ms. Irene Haas National Center for Advancing Translational Sciences (NCATS) Email: PMICPFOAInquiries@mail.nih.gov
Authority	Other Transaction awards will be made pursuant to current authorizing legislation.
PMI Cohort Program Other Transaction (OT) Policy Guide	Other Transaction awards are subject to the requirements of the *Other Transaction Award Policy Guide for the NIH Precision Medicine Initiative*. Applicants must review this policy guide, which is available by accessing: http://www.nih.gov/sites/default/files/research-training/initiatives/pmi/20151118-ot-award-policy-guide.pdf

Precision Medicine Initiative® Cohort Program Regional Medical Center Healthcare Provider Organizations

Background

In his State of the Union Address on January 20, 2015, President Obama announced his intention to launch the Precision Medicine Initiative® (PMI) "to bring us closer to curing diseases like cancer and diabetes, and to give all of us access to the personalized information we need to keep ourselves and our families healthier." In order to achieve the President's ambitious plan, the NIH PMI Cohort Program will build a national research cohort of one million or more U.S. volunteers that will provide the platform for expanding knowledge of precision medicine approaches and that will benefit the nation for many years to come.

In July 2016, the NIH issued awards for the PMI Cohort Program to build the foundational partnerships and infrastructure needed to launch the Cohort Program. The awards support a Data and Research Support Center, Participant Technologies Center, a network of Healthcare Provider Organizations (HPOs), and a Biobank.

The PMI Cohort Program values a highly interactive participation model, which is untested for a project of this scale. Participants will be the primary source of many research observations, providers of information about their health and experiences, consultants on proposed research studies, mediators of access to their healthcare data, contributors to overall data quality control, donators of data from

mobile and wearable devices, and recipients of their own as well as aggregate data and analysis results, according to their preferences.

Enrollment of PMI Cohort Program participants will be through two distinct approaches: one leveraging the strengths of HPOs with existing relationships with potential participants and the other opening enrollment directly to volunteers who are not part of a participating HPO. There are currently three types of HPOs within the PMI Cohort Program. The first type is the regional medical center (RMC) HPO; the second type is community health center HPO, such as Federally Qualified Health Centers (FQHCs); and the third type is the Veterans Administration Medical Center (VAMC) HPO.

In order to be a full participant in the PMI Cohort Program, all volunteers must provide an informed consent and agree to be re-contacted for future studies. They will be asked to complete brief survey modules, and must be willing to undergo a physical evaluation and submit biospecimens, including blood and urine, and to provide data from their EHR. These data will make up the core dataset and will be stored in a secure computing environment under rigorous standards to protect individual privacy. For the first year of the program, only volunteers 18 years or older will be eligible to participate; children will be included in the future. The Program will utilize a variety of data collection methods over the life of the Cohort Program, including mobile technologies, additional research questionnaires, collection of baseline and longitudinal data from EHRs, and collection and analyses of other biospecimens.

Purpose and Objectives of PMI Cohort Program Regional Medical Center Healthcare Provider Organizations

Through this funding opportunity, the NIH invites proposals from RMC HPOs to join the PMI Cohort Program consortium. This funding opportunity is open to integrated delivery networks (IDNs; defined as formal systems of providers and sites of care that provide both health care services and a health insurance plan to patients in a particular geographic area) and other large regional medical centers. Priority will be given to IDNs that provide an added benefit to the existing consortium through the geographic regions they serve, the diversity of their patient population, their substantial EHR data experience, their capacity, and other key experience and expertise that will allow for a quick start and to complement the current award recipients.

RMC HPOs responding to this funding opportunity are expected to have long-standing relationships of trust with their patients and to be able to make available a longitudinal record of care through their EHR. Among other responsibilities, HPOs contribute to the PMI Cohort Program by engaging, enrolling, and retaining participants, fostering study participation, collecting data and biospecimens, conducting physical evaluations, and cultivating ongoing participant engagement over the life of the Program. HPOs are expected to contribute to the goal of achieving a cohort that reflects the broad diversity of America. Individuals enrolled through RMC HPOs should be invited to participate regardless of disease status and should represent all life stages (children will be enrolled in the cohort in later years).

The PMI Cohort Program intends to have a national "launch" date to begin enrollment in the fall of this year. Successful applicants from this funding opportunity will be awarded prior to the launch date and will be a critical infusion of experienced teams to help solidify and finalize the Cohort Program activities for the launch and set a solid foundation for a successful 1 million or more cohort.

Other Transaction RMC HPO Approach

The Other Transaction award mechanism allows significant ongoing involvement from NIH staff and provides the NIH the flexibility to alter the course of the project in real-time to meet the overarching

goal. This may mean that awarded activity could be expanded, modified, partnered, not supported or discontinued based on program needs, emerging methods or approaches, and availability of funds. Performance during the award period will be reviewed on an ongoing basis and course corrections will be made as necessary. Based on programmatic review of the award milestones and activities, the successful awardees may be eligible to apply for a future FOA to continue as PMI Cohort Program partners to continue enrolling HPO-based participants into the PMI Cohort and furthering precision medicine research. Please note that the application process for the future funding opportunity may be concurrent with activities conducted during this award period.

Key Events	**Dates**	**Action needed by applicants**
Funding Announcement Posted	July 29, 2016	
Applications Due	August 29, 2016	Email completed application by 5pm local time
Review of written applications completed	September 7, 2016	
Reverse Site Visit	September 12 - 13, 2016	*Applicants participate in reverse site visit presentation
SAM and DUNS number submitted	September 12, 2016	**Candidates e-mail their DUNS number and SAM account information to PMICPFOAInquiries@mail.nih.gov
Estimated Award Date	September 30, 2016	

***Participation by the identified PI/PD is required.

**DUNS and SAM number registration can take several weeks, please see the registration link for helpful instructions. The registration link is specific to grants however the process for DUNS and SAM registration for this OT award is the same. Candidates should begin the registration process several weeks prior to this deadline to ensure completion in time to provide this information to NIH.

PMI Cohort Program Organization and Governance Structure

The PMI Cohort Program will function as a Consortium, with all awardees considered to be members of the Consortium with specific roles in its governance structure. For example, the PMI Cohort Program Steering Committee will consist of the Program Directors/Principal Investigators (PDs/PIs) from each of the awards. The Steering Committee will meet on a regular basis to share information on planning, recruitment progress, data and biospecimen collection, preliminary results, and analyses in progress. The PMI Cohort Program Consortium will include participant representatives in all aspects of its governance structure. Working groups will be established by the PMI Cohort Program Consortium Steering Committee to oversee the development and implementation of Consortium activities.

The PMI Cohort Program will have a single Institutional Review Board (IRB), to the extent permitted by law, constituted to ensure prompt and thoughtful consideration of the evolving protocols in the PMI Cohort Program and the central importance of participants as research partners. The PMI Cohort Program IRB will include representatives of the participant community.

Overview of Key Elements to Include in the Application

Applicants should describe how they will conduct the activities and collaborate across the Consortium as needed for each of the key elements described below:

1. Catchment area
2. Participant engagement plan
3. Physical evaluations and biospecimen collections
4. EHR data
5. Enrollment of 10,000 volunteers in the 12 month period of performance

The applicant must propose a well-defined set of milestones for each element and define the metrics for measuring them. Milestones should be provided in 4 month intervals and include quantitative monthly metrics over the one year period. In event of an award, the NIH staff will evaluate and negotiate a list of milestones for each interval of support.

Explanation of overall plans and activities for the key elements

In general, the key activities for the RMC HPO are described broadly as follows. Applicants must describe how each of these goals and components will be achieved successfully.

1. Catchment Area

Applicants should describe the catchment area and how the overall enrollment approach complements the PMI Cohort Program by:

a) Helping the PMI Cohort Program meet the goals to broadly reflect the diversity of the United States and to enroll and retain sufficient numbers of diverse populations and individuals (including all demographics, healthy people, people with existing disease, and people from all stages of life) to address scientific questions.
b) Representing geographic regions and populations that are currently not well-represented in the PMI Cohort Program, and/or provides a unique contribution to the Cohort Program.
c) Providing the services and infrastructure necessary to identify and enroll a diverse set of volunteers. This description should clearly articulate, with examples, how the applicant team has strong collaborative experience with the requisite technical, clinical, and administrative capabilities.
d) Representing a track record of success through other large-scale research efforts.
e) Contributing to the PMI Cohort Program consortium through the governance (steering committee, executive committee, and working groups), scientific, and operational means.

Applicants should plan and budget for three trips for all-hands steering committee meetings, and for weekly calls and team meetings as needed over the course of the award.

2. Participant Engagement Plan

Applicants should describe their participant engagement plan, which should reflect the following principles:

a) An inclusive philosophy of engagement that enables participation by individuals who have widely varying socioeconomic status, age, geography, health literacy, racial identity, ethnic heritage, personal competence with information technologies (including mobile technologies), and includes both healthy individuals and those with a wide range of health conditions and disabilities.
b) A philosophy about individual data access that includes immediate feedback to respondents on the data they have submitted as well as archival access to scientific data related to them as an individual that is maintained by the Program.

c) An expectation that cohort participants may be partners in the governance and design process, and may serve as testers of the technologies and methods.

With the anticipation of the national launch, applicants should plan to incorporate PMI Cohort Program designed outreach materials, web content, brands, etc. so that the messaging is consistent across the Program.

The Participant Engagement Lead will be responsible for overseeing all aspects of this plan, and should have experience working with community partners and patient advocacy groups. This plan must also identify and implement metrics for monitoring engagement activities and participant enrollment, as well as plans for remediation to ensure enrollment and retention stay the course.

3. Physical Evaluations and Biospecimen Collections

This activity has two main components: a) physical evaluation and b) biospecimen collection that are paired together due to the expectation that they will be conducted during a single visit from the participant.

Applicants should note that the protocols for physical evaluation and biospecimen collection are currently being developed by the PMI Cohort Program. It is expected that awardees under this funding opportunity will provide input and expertise prior to finalizing these protocols.

a) Component 1 - Physical evaluations. The physical evaluation may include: blood pressure (BP), heart rate, heart rhythm, body mass index, height, weight, and hip and waist circumference. Additional considerations for those aged 65 and older, newborns, and children may be included.

   Applicants should describe their plans to develop and/or test the IT and clinical infrastructure needed for collecting and transmitting the physical evaluation data. This will likely include interactions with the Data and Research Support Center and the Participant Technologies Center.

b) Component 2 – Biospecimen Collections. The Biobank will receive and store all PMI Cohort Program biospecimens collected from participants by HPOs and will distribute them to analysis laboratories as necessary to address future research questions. The RMC HPO will be responsible for working with the Biobank to implement the to-be-determined protocol for the collection, initial processing, and transfer of biospecimens to the Biobank. The Biobank will also be responsible for further processing, aliquoting, and storing the samples that are received.

   RMC HPOs are expected to collect biospecimens from enrolled participants according to the protocols that will be developed. A variety of collection tubes may be used, such as EDTA, lithium heparin, serum separator, acid citrate dextrose, and urine tubes, to allow for many types of analyses to be performed over the life of the PMI Cohort Program. The RMC HPOs may be required to perform minimal processing, including centrifugation when appropriate, prior to shipping the samples on the day of collection to the Biobank. This will enable the Biobank to process, aliquot, and store specimens within 24 hours of collection.

   Applicants should describe their plans to develop and/or test the IT and clinical infrastructure needed for specimen collection. Applicants should anticipate interactions with the Biobank and the Data and Research Support Center for this activity.

The RMC HPO should plan for, budget for, and identify clinical PMI Cohort Program work space, personnel to conduct the physical evaluation, and supplies for biospecimen collections.

In addition to these components, applicants must outline a process for scheduling physical evaluation and biospecimen collection visits with the member volunteers for the PMI Cohort Program. Please provide a flow diagram or an outline of how the RMC HPO will address scheduling visits for their members.

4. EHR Data

Applicants must be able to provide robust and comprehensive EHR data on participants, suggested elements to include in the submission are as follows:

a) Describe previous participation in large-scale studies that gather and integrate electronic data from heterogeneous sources, including EHRs, mobile health technologies, direct-to-participant mailings/web portals, administrative claims records, or other sources.

b) Document previous EHR data curation experience, and detail how the RMC will curate and provide a set of structured clinical data from study participants to the Data and Research Support Center at least quarterly, noting that the data are to be communicated via an agreed-upon Common Data Model (e.g., OMOP, PCORnet). To the extent practicable and possible, EHR data may include data from the time the volunteer became an HPO member and until the person leaves or decides not to participate in the PMI Cohort Program any longer.

c) Detail whether the HPO has accessibility to inpatient and outpatient data, electronic prescribing data, laboratory data, and electronic clinical documentation. Not all of these elements are required (e. g., an outpatient-only environment may be acceptable), and elements such as the diversity of the sample included may balance other weaknesses in these areas. Applicants should describe their familiarity with using EHR data for research and informatics as an important aspect of querying and standardizing transmittal to the Data and Research Support Center. Examples of data expected may include, but are not limited to:
    - All ICD and CPT codes with dates
    - Select, high-value clinical laboratory results in a structured form
    - All available lifetime medication data, including start date, stop date, dose, route, frequency, and strength
    - Vital measurements, including weight, height, heart rate, blood pressure, and pain score values
    - Record of all encounters, including dates of clinic visits, inpatient visits, emergency room visits.
    - Health plan data, enrollment and disenrollment dates, and whether coverage included medical benefits, pharmacy benefits, or both

d) Describe potential utilization of current and emerging standards to facilitate data exchange and analysis, such as:
    - Existing data standards to accept data from other HPOs, including best available standards or implementation specifications identified in the Office of the National Coordinator for Health Information Technology Interoperability Standards Advisory as "final" in regards to standards process maturity and required in regulation (including Medicare and Medicaid EHR Incentive Programs and Health IT Certification Rules).
    - Standards for capture and representation of family health history such as SNOMED CT and HL7 Version 3 Implementation Guide: Family History/Pedigree for familial relationships
    - HL7 DIGITIzE Actions Collaborative draft LOINC specification for pharmacogenomics

- HL7 Clinical Genomics WG standards including CDA R2 Clinical Genetics Reporting, Clinical Genomics Pedigree Model, HL7 Genetic Testing Results Message (V2), and Clinical Sequencing Domain Analysis Model (DAM)
- SMART on FHIR Genomics standards to support development of apps to communicate clinical genomics data between EHR systems
- Open ID Connect, OAuth and UMA for individual authorization and authentication
- More complete authorization standards (e.g., IHE, XUA, IUA, etc.) to ensure authorization standards are compatible across disparate networks
- Global Alliance for Genomics and Health (GA4GH) standards to address computable consent for research.

The EHR Lead will be responsible for all aspects of this plan. They should have experience in curating EHR data and implementing common data models. This plan must include how the RMC HPO will curate, format, and transfer data to the Data and Research Support Center, developing and testing the appropriated IT interfaces for this activity.

5. Enrollment of 10,000 volunteers in the 12 month period of performance
RMC HPOs will be expected to enroll 10,000 participants and foster participant retention, data collection, and continued engagement in the PMI Cohort Program. This activity should include at least the following elements:

a) Describe the plan for volunteer enrollments for each of the three 4-month intervals, such as the following (enrollment numbers for each interval proposed in the application should be well-justified):
   - 1st 4 months: 2,000 volunteers (note that the launch date will occur in this interval).
   - 2nd 4 months: 4,000 volunteers
   - 3rd 4 months: 4,000 volunteers

b) This plan must include the numbers of volunteers expected in each interval and stratified by key demographic characteristics, plans for obtaining informed consent (approved by the central PMI Cohort Program IRB), as well as plans and timelines for obtaining all baseline data necessary for the volunteer to become a "full participant' in the PMI Cohort Program. In order to be a full participant in the PMI Cohort Program, all volunteers must sign an informed consent and agree to be re-contacted for future studies, they will be asked to complete brief survey modules, to be willing to undergo a physical evaluation and submit biospecimens, including blood and urine, and to provide their EHR.

c) Describe how an engagement infrastructure will be established, and steps to ensure high retention rates, including the following:
   - Establish reporting metrics for each step in the enrollment process, from inquiry as a potential participant to a full cohort member.
   - Describe how overall enrollment data will be gathered and monitored/evaluated, including for specific populations and subgroups, such as those who are difficult to reach, or are underserved.
   - Describe expectations for baseline attrition rates for different demographics.

d) Provide a plan for how the RMC HPO will work with the Data and Research Support Center to ensure data integrity and participant continuity at the end of the period of support if the OT award is not able to continue, or if RMC enrollees wish to become Direct Volunteers.

e) For planning and feasibility purposes, applicants should briefly describe their anticipated ability to scale to enroll approximately 35,000 volunteers (including children) per year and expand the activities listed in this announcement.

f) Applicants familiar with returning results back to participants are encouraged to describe their experience, and their willingness and capabilities to provide genetic counseling in the future.

Administrative and Programmatic Reviews during the Award Period: Overall Timeline and Milestones

The accelerated components needed within this set of RMC HPOs during the period of support suggests that components may have to be developed concurrently that normally would be sequential. Thus, applicants are at liberty to construct a set of milestones and timelines that they believe are fitted to their capabilities and workflow, and have a high likelihood of being able to deliver a fully operational RMC during the 12 month period of support.

A timeline (Gantt chart) including milestones is required. Milestones are goals that must include clear and quantitative objective evaluation metrics. Milestones should be provided in 4 month intervals and include quantitative monthly metrics over the one year period. These milestones and metrics are required to provide clear indicators of the project's continued progress or emergent difficulties and will be used to evaluate award progress on an ongoing basis.

Regular reports will be required for NIH to assess progress. NIH will specify the report submission dates, format and data elements in the terms of the award. NIH will accomplish these reviews as quickly as practicable in order to avoid unnecessary delays. Milestone progression will be used to determine if activities supported by the award should be continued, modified, and/or discontinued.

Additional Requirements for Award

The NIH encourages the development and evaluation of innovative methods for intensive involvement by participants in the evolution of PMI Cohort Program participant-facing resources, study design and execution.

Among other important aspects of participant engagement are privacy, trust, and security. To this end, applicants must be in compliance with the following PMI Cohort Program Principles.

- Precision Medicine Initiative: Data Security Policy Principles and Framework: https://www.whitehouse.gov/sites/whitehouse.gov/files/documents/PMI_Security_Principles_Framework_v2.pdf
- Precision Medicine Initiative: Privacy and Trust Principles: https://www.whitehouse.gov/sites/default/files/microsites/finalpmiprivacyandtrustprinciples.pdf

Awards issued under this funding opportunity will be required to complete an IRB reliance agreement and acknowledge the exclusive use of the PMI Cohort Program central IRB, to the extent permissible by law.

Inventions and Patents

In order to promote the broad sharing of information and inventions in the PMI, awardee inventions will be governed by FAR clause 52.227-13, which provides title to the Government in any invention made under this award, subject to a revocable, nonexclusive, paid-up license in each patent application filed in any country on a subject invention and any resulting patent in which the government obtains title. This is to assure that patents directed to inventions made under this award cannot be used to block access by the research public to this important resource and associated technology.

Third Party Agreements, including subawardees, subcontracts, and vendors.

(1) The Awardee shall include the substance of this patent rights clause in all third party agreements for experimental, developmental, or research work. This patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the third parties (subcontractor, subawardees, and vendors) have all rights and obligations of the Awardee in the clause. The Awardee shall not, as part of the consideration for awarding the third party agreement, obtain rights in the third party's subject inventions.

(2) In the event of a refusal by a prospective third party to accept the clause, the Awardee—

a. Shall promptly submit a written notice to the PMI Agreements Officer setting forth the third party's reasons for such refusal and other pertinent information that may expedite disposition of the matter; and

b. Shall not proceed with such third party agreement without the written authorization of the PMI Agreements Officers.

(3) In third party agreements at any tier, the agency, the third party, and the Awardee agree that the mutual obligations of the parties created by the patent rights clause constitute a contract between the third party and the agency with respect to those matters covered by this clause.

(4) The Awardee shall promptly notify the PMI Agreements Officer in writing upon the award of any third party at any tier containing a patent rights clause by identifying the third party, the applicable patent rights clause, the work to be performed under the third party agreements, and the dates of award and estimated completion. Upon request of the PMI Agreements Officer, the Awardee shall furnish a copy of such third party agreement, and, no more frequently than annually, a listing of the third party activities that have been awarded.

Ownership of Data, Software, and Other Products

NIH will own all rights in data, software and other products (collectively "Works") made or developed under this award, subject to a paid-up, nonexclusive, irrevocable worldwide license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the awardee. The parties further agree that these Works are "works made for hire" as defined by the Copyright Act.

Award recipients agree that no commercial IP (e.g., data, software or other products), whether owned by the awardee or a third party except those specifically referenced in the application, will be utilized without express prior permission of NIH.

Human Subjects Requirements

The institution and personnel involved in the conduct of the research are required to comply with 45 CFR Part 46 and establish a reliance agreement with the PMI central IRB. The NIH will issue all awardees a Certificate of Confidentiality to protect against the compelled disclosure of personally identifiable information and to support and defend the authority of the Certificate against legal challenges.

Awarded entities will be required to provide assurance that the RMC HPO institution and partners are HIPAA covered entities, and/or are compliance with the privacy standards therein.

Termination/Expiration Requirement

A fundamental objective of this other transactions award announcement is to ensure that these valuable data and specimen resources remains available without interruption to the research public for many years to come, even in the event that awardees withdraw or are terminated or otherwise can no longer manage the resource, or when the associated scientific grants, discussed elsewhere in this FOA, are expired. NIH will own the biospecimens and related data and may take exclusive custody and control of them at its reasonable discretion. For purposes of this solicitation, "exclusive custody and control" means that upon termination or expiration of this award, the departing awardee and its partners may not retain or disclose a copy of any data, and may not establish a repository of any biospecimens (or portions thereof), acquired or generated under the award.